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Report Highlights:

The ultimate exporters' guide to the European Union providing information on labeling, packaging, additives, pesticides, certificates, GMOs, organic and functional foods, wine, etc.

Includes PSD changes: No

Includes Trade Matrix: No

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DISCLAIMER: This report has been prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service serving the U.S. Mission to the European Union in Brussels, Belgium for U.S. exporters of domestic food and agricultural products. While every possible care has been taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. **FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.**

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SECTION 1. FOOD LAWS

The European Union (EU), formerly known as the European Economic Community (EEC), was created by the Treaty of Rome on March 25, 1957, and after several accessions comprises currently 15 Member countries : France, Germany, Italy, Netherlands, Belgium, Luxembourg, Ireland, Denmark, the United Kingdom, Spain, Portugal, Greece, Austria, Sweden and Finland. Making up the world's largest multi-nation trading bloc, EU Member countries accept the entire body of EU laws and obligations associated with the treaties and agreements to which the EU is a party.

Originally created as a customs union, the EU slowly is becoming a single market. Harmonizing legislation between the 15 Member States, however, is a lengthy process, and by no means is the single market a *fait accompli*. It is important to note that when EU-wide legislation is incomplete or absent, the laws of Member States apply, often resulting in different rules in different Member States.

EU political structures include the permanent bureaucracy of the Commission, the Council of Member State representatives, and the European Parliament. All are involved in creating and passing legislation. For more information on how the EU works, see the website of the European Commission at <http://europa.eu.int/index-en.htm>.

EU legislation is made up of Directives and Regulations –all translated into the 11 official EU languages– which must be implemented at the Member State level. Directives define the result that must be achieved but leave to each Member State the choice of form and methods to transpose the directive into national laws (usually within 2-3 years after adoption). Regulations are binding in their entirety and automatically enter into force on a set date in all Member States. Directives are more common than regulations. Amendments to EU legislation are usually published in new and separate Directives and Regulations, making it difficult to be sure of all possible amendments when doing research. When legislation is referenced in this guide, it is implied that all further amendments also apply.

Harmonizing food and food safety legislation has become politically challenging in the aftermath of the BSE (Mad Cow disease) crisis and other more recent food safety scandals. To date, although most framework directives exist, many specific directives still need to be drawn up and adopted: e.g. specific directives on food contact materials and on foods for particular nutritional uses.

The EU has followed a dual approach in harmonizing food laws: "horizontal" legislation that covers aspects which are common to all foodstuffs (such as additives, labeling and hygiene, etc.) and "vertical" legislation on specific products (e.g., cocoa and chocolate products, sugars, honey, fruit juices, fruit jams, etc.). Still under discussion are legislative initiatives for issues such as standards for vitamins, fortified foods (allowed in some Member States and prohibited in others), minerals, certain pesticide residues and requirements for allergen labeling.

Imported products must meet existing Member State requirements in cases where EU regulatory harmonization is not yet complete.

The main principle of the single market concept is to ensure that all food products, whether produced in the EU or imported from a third country, can move freely throughout the EU if they comply with the directives. In reality, certain directives allow Member States to make exceptions e.g. in cases where a country can prove health concerns about a product intended for import. Free movement can only be guaranteed when all aspects are covered by harmonized legislation: e.g. a foodstuff may comply with the labeling directive but be pre-packed in a material for which harmonized rules do not yet exist.

Enforcement of EU food legislation is done by Member State officials. Auditing oversight of Member State performance is done by EU Commission officials in Brussels. The EU Commission has the power to initiate legal action in the European Court of Justice against Member States who are not complying with EU Directives and Regulations.

Exporters should be aware that there may also be some variation among Member States in applying EU harmonized legislation: this may be due to variations in the transitional period needed to adjust to EU rules; there may be temporary waivers or exemptions –usually called derogations; in certain cases there may be room for interpretation of EU harmonized legislation; certain aspects which are not regulated in detail at EU level may be handled differently in different Member States, e.g. acceptability of stick-on labels varies among Member States. Also, there is a wide variation in inspection fees, in registration fees and in the time required to evaluate dossiers on products used in the course of the food production process.

FAIRS reports prepared by the Office of Agricultural Affairs in each Member State are a good source of information and can be found at <http://www.fas.usda.gov/itp/ofsts/fairs-country.html>.

AS A REMINDER! Imports of red meat, bovine embryos and semen, farm and wild game meat, meat products, milk and milk products and porcine semen to the EU from the United States may only originate from EU approved U.S. establishments (see Section 9.A).

FAS/USEU maintains lists of approved establishments as well as general information on EU import duties and quotas which can be found on our website at <http://www.useu.be/agri/Export.html>. The website is also hot linked to additional sources of useful information.

SECTION 2. LABELING REQUIREMENTS (www.useu.be/agri/label.html)

A. General Requirements

The standard U.S. label fails to comply with EU labeling requirements.

The main rules on the labeling, presentation and advertising of foodstuffs marketed in the EU are laid down in Council Directive 79/112/EEC, as amended. This directive applies not only to foodstuffs intended for sale to the ultimate consumer but also for supply to restaurants, hospitals and other mass caterers. This general directive has been amended many times.

Compulsory Information

- the name under which the product is sold
- the list of ingredients, in descending order of weight. Important exceptions include added water in foods reconstituted from concentrates, and cheese, which is covered by special rules. As concerns about allergens rise, it should be noted that sub-ingredients of an ingredient constituting less than 25 percent of the finished product do not need to be listed separately, e.g. if ten percent of a packaged salad is mayonnaise, the label need not break out the oil or eggs that make up the mayonnaise.
- certain ingredients may be designated by the name of the category rather than the specific name. These include fats, oils, starch, fish, cheese, spices, herbs, gum bases, crumbs, sugar, dextrose, glucose syrup, milk proteins, cocoa butter, crystallized fruit, vegetables and wine. Indication of the presence of genetically modified (GM) ingredients is obligatory, but no EU harmonized standard terminology has been developed (see section 7).
- the quantity of certain ingredients or categories of ingredients (QUID) *See below*
- the net quantity of prepackaged foodstuffs expressed in metric units (liter, centiliter, milliliter, kilogram or gram).
- the shelf life is indicated by the words "Best before..." when the date includes an indication of the day, or by "Best before end of..." in other cases. The date has to be given in order of day- month-year. However, for foodstuffs with a shelf life of less than three months, the day and month of expiry are adequate; for a shelf life of three to eighteen months the month and year are sufficient; for more than eighteen months shelf life the year is sufficient indication.
In the case of highly perishable foodstuffs the date consisting of the day, the month and possibly the year has to be preceded by the words "use by."
- any special storage conditions or conditions of use

- the name or business name and address of the manufacturer, packager or vendor established within the Community
- particulars of the place of origin or provenance in case absence of such information might mislead the consumer
- instructions for use
- the actual alcoholic strength for beverages containing more than 1.2 percent alcohol by volume
- a mark to identify the lot to which a foodstuff belongs, determined by the producer, manufacturer or packager or by the first seller in the EU. The marking shall be preceded by the letter "L" except in cases when it is clearly distinguishable from other indications on the label. The lot identification is not necessary if the date (day and month) of minimum durability or "use by" date, appears in uncoded form on the label.
- treatments undergone, with specific indications for irradiated foods and deep-frozen foods (see section 7)

Additives

- the labeling directive lists the categories of additives which must be designated by the name of their category followed by their specific name or EEC number. The categories are the following: color, preservative, anti-oxidant, emulsifier, thickener, gelling agent, stabilizer, flavor enhancer, acid, acidity regulator, anti-caking agent, modified starch, sweetener, raising agent, anti-foaming agent, glazing agent, emulsifying salts, flour treatment agent, firming agent, humectant, bulking agent, propellant gas.
- flavorings: the labeling directive describes the way of designating flavorings in the list of ingredients.
- the presence of sweeteners/aspartame/polyols requires standardized Statements on the label; packaging gases are not considered as additive but also require a standardized Statement

Quantitative Ingredients Declaration (QUID)

Directive 97/4/EC (amending general labeling Directive 79/112/EEC) introduces the compulsory quantitative ingredients declaration (QUID) in the following cases:

- where the ingredient or category of ingredients appears in the name under which the foodstuff is sold: e.g.
"15% strawberries" on strawberry ice cream - QUID for strawberries
"35% fruit" on fruit pie - QUID for total fruit content
- where the ingredient or category of ingredients is usually associated with that name by the consumer: e.g.
goulash soup - QUID for beef

- where the ingredient or category of ingredients is emphasized on the labeling in words (e.g. "made with butter"), pictures (e.g. of a cow to emphasize dairy ingredients) or graphics (different size, color and/or style of print)
- where the ingredient or category of ingredients is essential to characterize a foodstuff and to distinguish it from similar products

The QUID declaration must be indicated in or immediately next to the name under which the product is sold, unless a list of ingredients is voluntarily indicated on the label in which case the quantity may appear in the list. The quantity of the ingredient, expressed as a percentage, must correspond to the quantity of the ingredient(s) actually used in the preparation of the product.

The QUID requirement DOES NOT apply to constituents naturally present in foods and which have not been added as ingredients e.g. caffeine (in coffee) and vitamins and minerals (in fruit juices). QUID declarations are not needed in a number of cases, e.g. when products State the drained net weight or where an ingredient is used for purposes of flavoring. QUID declarations CANNOT replace nutrition labeling.

Commission Directive 1999/10/EC provides for exemptions from the QUID requirement:

- when the wording "with sweeteners" or "with sugar(s) and sweetener(s) accompanies the name under which a foodstuff is sold
- when the addition of vitamins and minerals is subject to nutrition labeling
- when foodstuffs are concentrated or dehydrated

General guidelines have been drawn up to help Member States and industry organizations implement the principle of QUID. A copy of these guidelines can be obtained from our office upon request.

Language Requirements

Labeling has to be in a language easily understood by consumers; this is in practice the official language(s) of the Member State. Multi-language labeling is allowed throughout the EU.

Stick-on Labels

EU legislation does not contain any reference to the use of stick-on labels. It is up to individual Member States to accept stick-on labels.

Samples

EU legislation covers all foods destined for consumption. It does not contain any specific labeling requirements or exemptions for samples.

B. Requirements Specific to Nutritional Labeling

Medical claims, attributing to a foodstuff the property of preventing, treating or curing human diseases, are explicitly prohibited in the EU general labeling directive. However, this directive does not provide any guidance on which health claims (e.g. "Aids Digestion") are allowed and which are not. As a result, many EU Member States have developed separate initiatives in this area.

Nutrition labeling is not mandatory in the EU unless a nutrition claim is made on the label or in advertising messages. "Nutrition labeling" means any information on the label that relates to energy value and to the following nutrients: protein, carbohydrate, fat, fibre, sodium, vitamins and minerals present in significant amounts. A "nutrition claim" means any representation or advertising that claims that a foodstuff has particular nutritional properties and is only allowed if it relates to the energy value and/or nutrients referred to above. Nutrition labeling rules are laid down in Council Directive 90/496/EEC.

Where nutritional labeling is provided, the information to be given should consist of either group 1 or group 2 in the following order:

Group 1: - the energy value
 - the amount of protein, carbohydrate and fat

Group 2: - the energy value
 - the amount of protein, carbohydrate, sugar, fat, saturates, fibre and sodium

The energy value and the proportion of nutrients must be declared in specific units per 100 grams or per 100 milliliters. Information on vitamins and minerals must be expressed as a percentage of the recommended daily allowance (RDA).

The information on the label must be presented in tabular form with the numbers aligned or if space does not permit, in linear form in a language easily understood by the purchaser.

C. Product-Specific Labeling

For a number of products, specific labeling requirements have been established in addition to the general requirements described above. These include:

- novel foods

- foodstuffs for particular nutritional uses including dietetic and baby/infant foods
- wine
- spirit drinks
- organic foods
- cocoa and chocolate products, sugars, honey, fruit juices and similar products, preserved milk, coffee extracts and chicory extracts, fruit jam, jellies, marmalades, and chestnut puree

More details on above products can be found in Section 7.

- fresh fruits and vegetables
- meat, eggs, dairy products, spreadable fats

SECTION 3. PACKAGING AND CONTAINER REQUIREMENTS

A. Container Contents

Unlike the other requirements covered by this guide, requirements in the Directives concerning container contents of pre-packaged products set out below are not a prerequisite for marketing a foodstuff. However, if these requirements are satisfied, free movement throughout the EU is guaranteed.

The maximum tolerable error between the actual content and the quantity indicated on the label, and methods to check this are fixed in Council Directive 76/211/EEC, as amended. A small "e" of at least 3 mm on the label guarantees that the actual content corresponds to the quantity indicated. The size of the figures indicating the quantity depends on the nominal quantity:

nominal quantity greater than 1000 g or 100 cl: at least 6 mm high; greater than 200 g/20 cl but less than 1000 g/100 cl: at least 4 mm; greater than 50 g/5 cl but less than 200 g/20 cl: at least 3 mm; less than 50 g/2 cl: 2 mm. The size is followed by the unit of measurement.

Container sizes have been prescribed for butter, fresh cheeses, salt, sugar, breakfast cereals, pasta, rice, dried fruits and vegetables, coffee, frozen fruits and vegetables, fish fillets, fish fingers, ice-cream, preserved fruits and vegetables and products sold in metal containers. (Council Directive 80/232/EEC)

B. Packaging Waste Management

Member States are required to take measures to reduce packaging waste and must introduce systems for reuse, recovery and recycling of packaging materials (Council Directive 94/62/EC). To facilitate collection, reuse and recovery including recycling, an identification system for packaging has been drawn up (Commission Decision 97/129/EC). Its use is voluntary.

C. Materials in Contact with Foodstuffs

Council Directive 89/109/EEC specifies the common rules for materials that come into contact with foodstuffs and provides for the adoption of specific directives including lists of authorized substances, conditions of use, migration limits, purity standards. To date, specific directives have been developed for vinyl chloride, plastics, regenerated cellulose film, ceramics. In the case of ceramics, migration limits have been established for two of their constituents, namely lead and cadmium. Materials must bear an indication "for food use", which can be replaced by the specific symbol designed in Council Directive 80/590/EEC. Exporters are advised to verify if a Member State follows EU provisions as Member States are allowed to authorize provisionally the use of certain

substances not listed in one of the specific directives and, for reasons of public health, they may also restrict or temporarily prohibit the use of certain materials authorized by the specific directives.

SECTION 4. FOOD ADDITIVE REGULATIONS

(www.useu.be/agri/additive.html)

Council Directive 89/107/EEC provides for the establishment of EU harmonized positive lists --lists of what is permitted-- of a wide range of food additives. All food additives not included in the positive lists are prohibited except for those new food additives that get a temporary two year authorization by Member States. Processing aids and flavorings fall outside of the scope of this directive. *Also, substances added to foodstuffs as nutrients such as minerals, trace elements, vitamins do not fall under the scope of this directive and continue to be subject to Member States legislation.*

The lists of authorized food additives and their conditions for use are published in three directives:

1) European Parliament and Council Directive 94/35/EC on sweeteners for use in foodstuffs. The annex to this directive lists maximum usable doses for sweeteners in selected foodstuffs.

2) European Parliament and Council Directive 94/36/EC on colors for use in foodstuffs.

Annex I: list of permitted food colors. Only substances listed in this annex may be used

Annex II: foodstuffs which may not contain added colors

Annex III: foodstuffs to which only certain permitted colors may be added

Annex IV: colors permitted for certain uses only

Annex V: colors permitted in general and the conditions of use therefore. Colors permitted following the "quantum satis" principle (no maximum specified) are listed in the Appendix

3) European Parliament and Council Directive 95/2/EC, as amended, the so-called miscellaneous additives directive on food additives other than colors and sweeteners.

Annex I: list of food additives permitted for use in foodstuffs (excl. those listed in Annex II) following the "quantum satis" principle - see Appendix

Annex II: list of foodstuffs in which only a limited number of additives of Annex I may be used. These include cocoa and chocolate products, fruit juices and nectars, jam and jelly, dehydrated milk and cream, fruits and vegetables, rice, oils and fats, certain cheeses, minced meat, bread and pasta, wines and beer

Annex III: list of conditionally permitted preservatives and antioxidants

Annex IV: list of other permitted additives

Annex V: list of permitted carriers and carrier solvents

Annex VI: list of additives permitted in foods for infants and young children

An important difference from U.S. legislation is the acceptance of flour bleaching agents: chlorine, bromates and peroxides are not allowed in the EU.

Specific information on authorized additives can be obtained from the Office of Food Safety and Technical Services or from our office. Upon request, our office can also provide a multilingual list of all food additives.

Labeling requirements for additives and flavorings are laid down in the general labeling directive. *See also Section 2*

The addition of a new food additives to the EU positive list is a lengthy process. However, any Member State can allow the domestic use of a new food additive on their territory for a two year period. Companies are advised to submit an application to the Member State where they want to start using a new additive and simultaneously to the Commission. Procedures on obtaining the 2-year waiver differ from one Member State to another, and the time necessary to obtain approval also can vary significantly. The procedure for inclusion of an additive in the positive list requires that a dossier be sent to the EU Scientific Committee and to the Commission. The EU Scientific Committee reviews a substance and has to give a positive opinion before the Commission can propose the addition to the positive list. The Scientific Committee review takes a minimum of one year; the procedure to adopt a substance proposed by the Commission takes at least 18 months. Guidelines on preparing an application dossier requesting authorization of an additive can be obtained from our office.

Processing Aids

A list of extraction solvents allowed in the production of foodstuffs and food ingredients, along with their conditions of use has been established in Council Directive 88/344/EC.

Flavorings

In an initial step to harmonize the use of flavorings in the EU, the European Commission has compiled a register of all flavoring substances authorized in the different EU Member States. Substances which are subject to restrictive or prohibitive measures in certain Member States have been marked. The register is available from our office.

SECTION 5. PESTICIDE AND OTHER CONTAMINANTS **(www.useu.be/agri/pesticides.html)**

The legislation on pesticides and contaminants is partially harmonized in the EU. Enforcement of both EU and remaining Member State rules is done at the Member State level.

Pesticides

EU pesticide legislation has not been fully harmonized yet and is under review. Community maximum residue levels (MRL's) take into account the work done by Codex Alimentarius and by the OECD but exceptions exist. An overview of all compounds for which harmonized MRL's have been developed are available from our website. The complete list of MRL/ commodity combinations can be downloaded from the Commission's webserver at:

http://europa.eu.int/comm/dg06/phyt/residues/index_en.htm. Pesticide MRL's for processed or composite products are based on the MRL's for the raw agricultural ingredients.

For the registration of a new pesticide in the EU, including the establishment of an MRL, an application needs to be prepared and reviewed by the relevant authorities and committees at Member State and EU level. For pesticides which are not or no longer authorized at Community level, an import tolerance may be requested. Application dossiers are first submitted to a rapporteur Member State. The complete procedure is described on the Commission's webserver at: http://europa.eu.int/comm/dg06/phyt/residues/index_en.htm.

Compounds for which there is no harmonized MRL yet remain subject to Member State legislation.

Other Contaminants

The EU has set maximum levels for nitrate residues permitted on lettuce and spinach and for aflatoxin in peanuts, nuts, dried fruits, cereals and milk (Commission Regulation 194/97, as amended). A harmonized sampling plan for aflatoxins has been developed but not applied throughout the EU yet (Commission Directive 98/53/EC).

Member States requirements continue to apply for a number of other contaminants such as heavy metals, certain other mycotoxins, and radioactive elements.

Residues in Animals and Animal Product

The monitoring of residues in animals and animal products is addressed separately in Council Directive 96/23/EC. This directive includes the monitoring of the above-mentioned pesticide residues but includes also

the monitoring of residues of veterinary drugs and a wide range of other contaminants and undesired substances such as residues of growth promotants. The prohibition of the use of hormones in meat production is addressed in Council Directive 96/22/EEC.

SECTION 6. OTHER REGULATIONS AND REQUIREMENTS

A. Product Inspection and Registration

Member States are responsible for carrying out inspections on a regular basis and in cases where non-compliance is suspected. Products can be checked at import or at all further stages of marketing. In case of non-compliance, the EU hygiene directive (Com. Reg. 93/43/EEC) allows the Commission to suspend imports from third countries or introduce special conditions for products from the third country concerned, applicable on the entire EU territory.

Criteria for laboratories conducting food controls have been harmonized but it is the Member States' responsibility to designate laboratories that are allowed to perform analyses (Council Directives 89/397/EEC and 93/99/EEC).

Specific detailed inspection requirements exist for animal products. Inspections are done under supervision of a veterinarian at a limited list of ports and border inspection posts. Fresh fruits and vegetables are subject to phytosanitary controls and are checked for compliance with EU-harmonized marketing standards. These have been established for apples and pears, apricots, artichokes, asparagus, aubergines (eggplant), avocados, beans, brussels sprouts, cabbage, carrots, cauliflowers, celery, cherries, citrus fruit, courgettes (zucchini), cucumbers, garlic, kiwis, leeks, lettuce, curly and escarole chicory, melons, onions, peaches and nectarines, peas for shelling, plums, spinach, strawberries, sweet peppers, table grapes, tomatoes, watermelons, witloof chicory.

Product samples have to comply with the food regulations applicable in the EU. Exemptions exist for meat and meat products, for which a waiver may be obtained from the listing requirement described below.

Inspection fees differ from one Member State to another. Measures in case of non-compliance also vary widely, ranging from non-admittance of a product to forced destruction. This may be a decisive factor in choosing a port of entry for products where problems are more likely.

Generally, there is no EU requirement to register imported foods except for the introduction of novel foods (see section 7). The person/company introducing a novel food has to submit a request to the authorities in the Member States where the product will be marketed and a copy of this request has to be sent to the Commission's Enterprise Directorate. Importers of organic products (see section 7) are required to notify the competent regulatory authority of the Member State of their activity. The introduction of foodstuffs with particular nutritional uses (PARNUTS - see section 7.B) needs to be notified to the Member State where the food is sold. Exporters of vitamin-enriched foods or nutritional supplements are especially advised to check for the existence of specific Member State registration or notification requirements.

B. Certification and Documentation Requirements

AGRIM Certificates

The EU requires import licences (AGRIM certificates) for most agricultural products for which it provides market support, including grains, milk, meat, olive oil, many fruits and vegetables, wine and sugar. In order to obtain a licence an application form must be submitted and security fee must be paid to the issuing Member State. Licences vary in validity with most expiring three months after the month of issuance.

Health Certificates

Plant Products. Phytosanitary certificates issued by APHIS have to accompany fruit, vegetable and nut shipments to the EU.

Animal Products (www.useu.be/agri/certification.html)

The European Community is in the process of harmonizing legislation on imports of animal products. This is a three-stage process that starts with the recognition of a country to export a certain animal product. The U.S. is recognized by the EU for nearly all animal products.

In a second stage, lists of EU approved establishments are drawn up in recognized countries. Various U.S. agencies, including FSIS, APHIS, AMS, and FDA are involved in the listing process. Depending on the commodity, establishments are subject to EU inspections prior to listing and/or to occasional EU audits after listing. Exporters should be aware that getting a plant listed can take several months. At present, the following products must come from an EU-approved establishments: red meat, meat products, milk & milk products, wild game meat, farmed game meat, bovine embryos, bovine semen, porcine semen, animal casings, fish and fishery products, including processed bivalve molluscs and live bivalve molluscs. Lists (except fish and fishery products) are available at www.useu.be/agri/estab.html

The third level is the requirement that all shipments be accompanied by animal health and/or public health certificates signed by U.S. officials to guarantee that individual lots or shipments of products meet Community requirements.

For other products the Community has not yet completed harmonization of import requirements. In these cases import regulations are still under the control of the individual Member States. This often results in the 15 Member States maintaining different sets of lists of third countries, lists of establishments, certificate requirements, and inspection programs.

Contact information for the agencies issuing export certificates is available from our website.

Foods containing Animal Products (www.useu.be/agri/foodcertif.html)

All animal products imported into the EU need animal or public health certification. For foods containing animal product, the situation is more complicated because there is no legislation specifying the percentage of dairy, egg, red meat or poultry meat that a foodstuff must contain to necessitate certification. However, the specific EU legislation applicable to the animal product in question contains certain provisions on certification.

Red meat & poultry meat: Products containing any amount of red meat or poultry meat must be certified.

Egg products & dairy: Certification of products containing egg products or dairy products depends on the composition of the product in relation to the definitions in the relevant Community legislation.

As a rough guideline, if foodstuffs contain more than 50 percent of egg products/dairy products, the Commission believes they should be considered as such. More details are available from our website. Further, the competent authorities of the importing EU Member State should be contacted for their interpretation of the Commission's guidelines.

SECTION 7. OTHER SPECIFIC STANDARDS

A. Novel Foods/Genetically Modified Foods (GMOs) (www.useu.be/agri/biotech.html)

Biotechnology has become a controversial issue in Europe. For information see our website.

Three laws currently govern the regulatory review and commercialization of genetically-modified foods in the EU.

Environmental Directive 90/220 governs the approval for environmental release and commercialization of "living" genetically-modified organisms. This includes seeds and therefore whole corn and soybeans, but not processed products. Three corn varieties, the Monsanto Roundup ready soybean, and several other crops have been approved under 90/220. Several more approvals are pending. The competent authority is the Environmental Directorate.

The Enterprise Directorate (formerly DG III) administers the Novel Foods Regulation (EP & Council Reg. 258/97) governing food safety assessments and labeling for most genetically-modified foods. The regulation requires labeling of all new processed foods and food ingredients, including those made from GMO's. The regulation lacks implementing detail, so it is up to each Member State to determine thresholds, testing methods, and what products to test.

Products need not have received full Novel Foods approvals to be placed on the market as long as an application has been made and all Member States have been notified.

A third regulation (Council Reg. 1139/98) in force from September 1998 covers labeling of foodstuffs derived from Round-Up Ready soybeans and Novartis Bt-176 corn, as these products were commercialized before the Novel Foods law went into effect. This regulation also was issued without implementation details, but recently the Commission has proposed an amendment setting a one percent threshold for adventitious (accidental) contamination. This amendment has not yet made it through the regulatory process, and if passed, would apply only to products for which the manufacturer could show best efforts at sourcing non-GMO ingredients.

None of these regulations make clear which products processed from GMO's must be labeled, what testing methods apply, or even how a product can be determined "GMO-free".

Exporters should work with Member States authorities to register their product and to obtain insight in the Member States' interpretation of these indistinct EU rules.

B. Dietetic or Special Use Foods (www.useu.be/agri/partnutr.html)

Council Directive 89/398/EEC is a framework directive laying down rules for foodstuffs intended for particular nutritional uses (PARNUTS). These are foodstuffs which, due to their special composition or manufacturing process, can clearly be distinguished from foodstuffs for normal consumption.

Provisions including compositional and hygiene requirements, provisions regarding the quality of raw materials, a list of additives/substances, specific labeling requirements, sampling procedures and analysis methods have been laid down in specific directives for four product categories:

- 1) Commission Directive 96/5/EC on processed cereal-based foods and baby foods for infants and young children.
- 2) Commission Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction.
- 3) Commission Directive 91/321/EC on infant formula and follow-on formula.
- 4) Commission Directive 1999/21/EC on dietary foods for special medical purposes.

To take advantage of technological developments, the Commission may authorize the marketing of products which do not comply with the requirements of the specific directives for a two-year period.

A fifth specific directive on foods and beverages for athletes will be drafted in the future. No decision has been made yet if a specific directive will be developed for foods intended for diabetics. Meanwhile, these foodstuffs remain subject to Member State legislation. The introduction of foodstuffs intended for particular nutritional uses for which no specific rules are set must be notified to the Member State where the food is sold.

C. Wine, Beer and Other Alcoholic Beverages

The United States and the EU are in the midst of negotiating a bilateral agreement on wine. Exports of U.S. wine to the EU continue under derogations which permit U.S. oenological practices. The current derogations for U.S. wine making practices and certification will expire in December 2003 (Council Regulation 2839/98), or when a new wine accord is concluded. A major issue of concern for the EU is the use by some U.S. vintners of geographical indications, e.g. "Burgundy" or "Champagne". The EU has indicated that it is of critical importance to protect their own geographical indications. Many U.S. vintners have already moved away from using European geographical indications.

All U.S. wine imports must be accompanied with documentation (the certificate and analysis report or VII-form) that certifies its origin and that it meets EU standards. Under the current regulation the producers may issue the certification themselves if they provide certain assurances. Council Regulation 2390/89 outlines the general rules for the import of wine, grape juice and grape must. Council Regulation 1576/89 as amended, lays down the general rules on the definition, description and presentation of spirit drinks. There is no Community legislation for beer; although some Member States have adopted national provisions to make the list of

ingredients compulsory.

D. Organic Foods

The production, labeling and importation of organic foods is covered by Council Regulation 2092/91, as amended. Regulation 1804/99 covers livestock products. The word “organic” on the label may only be used for product conforming with this regulation. Products imported from the U.S. need to be certified and exporters must work through individual Member States to obtain clearances to import certified organic products on a case-by-case basis.

EU organic products legislation requires that organic product certifiers meet criteria as certification bodies defined by EN 45011/ISO Guide 65. Member States are implementing this requirement. USDA’s Agricultural Marketing Service (AMS) has developed a program to accredit U.S. organic certifiers to the ISO Guide 65 requirement. To date the Netherlands, Denmark, the UK, France and Germany have said that they will accept AMS accreditation of certifiers, but U.S. exporters must continue to satisfy Member State requirements.

E. Vertical legislation (www.useu.be/agri/vertic.html)

Vertical legislation on the manufacture and marketing of specific products has been developed for cocoa and chocolate products (directive 73/241/EEC), sugars (directive 73/437/EEC), honey (directive 74/409/EEC), fruit juices and similar products (directive 93/77/EEC), preserved milk (directive 76/118/EEC), coffee extracts and chicory extracts (directives 77/436/EEC and 1999/4/EC), fruit jams and similar products (directive 79/693/EEC).

F. Animal Products

- Council Regulation 1907/90 establishes marketing standards for eggs
- Council Regulation (EEC) No 1906/90 of 26 June 1990 on certain marketing standards for poultry
- Council Regulation 1898/97 limits the use of the word "milk" or other dairy products to actual dairy products
- Council Regulation 2991/94 establishes standards for spreadable fats
- Council Regulation 2406/96 of 26 November 1996 laying down common marketing standards for certain fishery products

G. Frozen Foodstuffs (www.useu.be/agri/frozen.html)

Council Directive 89/108/EEC sets rules for quick-frozen foodstuffs and for their packaging and labeling. Quick-frozen foodstuffs sold to the final consumer should carry the following additional labeling indications: the product name with the indication “quick-frozen”, the date of minimum shelf life, the period during which the purchaser may store the product, the storage temperature and/or type of storage equipment required, batch

identification and a clear indication of the type “do not refreeze after defrosting”.

H. Irradiated Foodstuffs (www.useu.be/agri/irradiation.html)

A harmonized labeling requirement for irradiated food stating "irradiated" or "treated with ionizing radiation" exists in the EU. Any further harmonization of EU rules on food irradiation is still at an initial stage (Directives 1999/2/EC and 1999/3/EC) . Member States are expected to allow the marketing of dried aromatic herbs, spices and vegetable seasonings treated with ionizing radiation throughout the EU by September 2000, at that time the labeling requirement will become obligatory to indicate irradiated ingredients used in compound ingredients constituting less than 25 % of the finished product. U.S. exporters should check with the Member States where they are marketing their product to see if the new rules already have been implemented. Until the initial positive list is expanded, exporters should also check for any national rules allowing irradiation of products in addition to aromatic herbs, spices and vegetable seasonings.

SECTION 8. COPYRIGHT AND /OR TRADEMARK LAWS (www.useu.be/agri/commu.html)

Community trademark policy was created by Council Regulation 40/94 and implemented by Commission Regulation 2868/95. This regulation creates a single, unitary registration system covering the whole Community territory.

In practice, a Community trademark must meet two conditions: it must be a sign which can be represented in graphic form, and it must make it possible to distinguish goods and services from those of another company. It is valid for a period of 10 years. Applications for registering Community trademarks under these regulations may be filed with the Alicante, Spain, based Office of Harmonization for the Internal Market, subject to the fees set out in Commission Regulation 2869/95, or at a national industrial property office in a Member State of the European Union.

On completion of the registration procedure, the trademark is registered in the Register of Community trademarks.

Before the introduction of the Community trademark, two different systems were in place for registering trademarks in countries of the European Union. First, companies had the option of applying for an international trademark that applies in the countries which have signed the Treaty of Madrid. However, the U.S. did not sign this convention and only the following nine EU countries signed it: Belgium, Germany, Spain, France, Italy, Luxembourg, the Netherlands, Austria and Portugal. The second option was to apply for national trademarks in the individual countries of the EU. However, the only means for protection of a trademark for the whole Community territory was to file twelve applications for the registration of the mark at the national trademark offices of the respective Member States plus an application at the common trade mark office of the three Benelux countries, dealing with a total of thirteen different trademark registration systems in eleven different languages.

With the introduction of Community trademarks, a third system was added and Community, national and international trademarks co-exist within the Member countries of the European Union.

SECTION 9. IMPORT PROCEDURES

(www.useu.be/agri/duties.html)

In general, Community Customs rule have been applied uniformly throughout the customs territory of the European Union since the adoption of Council Regulation 2913/92 which establishes the Community Customs Code (CCC). This regulation specifies that any person may appoint a representative in his dealings with customs authorities. Goods are only released after the payment of the import duty, which is independent of the point of entry. The duty is determined by the classification of goods using the combined nomenclature (CN) of goods and by the customs value. The customs value is the CIF price at the European border derived from the product price found on the invoice and the transportation costs reflected in the airway bill or the bill of lading. Other customs procedures are described in detail in the CCC including entry into free zones, situations where no import duty is payable: e.g. the inward processing regime, under which goods can be imported for processing but the finished product must be exported from the Community market.

The code provides for a two-stage right of appeal lodged in the Member State where a decision has been taken or applied for: in the first instance to the customs authority, then to the national courts.

It should be noted that usually other taxes such as the value added tax (VAT), excise duties, environmental taxes and inspection fees also are collected upon import. None of these taxes, however, have been harmonized.

APPENDIX I. GOVERNMENT REGULATORY AGENCY CONTACTS

Office for Harmonization in the Internal Market
Avenida de Aguilera, 20
03080 Alicante
Spain
Tel. (34-96) 513 93 33
Fax. (34-96) 513 13 44

As a major reorganization of the directorates-general is currently taking place, it is advisable to get in touch with our office for specific contact information

Commission of the European Communities
Rue de la Loi 200
1049 Brussels
Belgium

USDA/FDA contacts for certification of Animal Products (www.useu.be/agri/certification.html)

Other FAS Offices in the European Union (www.useu.be/agri/other.html)

APPENDIX II. HOW TO OBTAIN EU LEGISLATION (www.useu.be/agri/legis.html)

FREE OF CHARGE

- Official Journal
- Treaties
- Legislation in force
- Consolidated texts
- Preparatory Acts
- Case Law

AGAINST PAYMENT

- Celex database
- Document delivery service
- Sales offices

FREE OF CHARGE

The Official Journal

The Official Journal is the EU equivalent of the U.S. Government's "Federal Register". The L (Legislation) and C (Information and Notices) series of the Official Journal appear daily. Full texts in the 11 official languages of the European Union, including tables and graphics, are available for a period of 45 days following publication on the "Eur-lex website".

<http://europa.eu.int/eur-lex/en/oj/index.html>

Treaties

Consolidated texts of treaties and treaties in the process of ratification are available.

<http://europa.eu.int/eur-lex/en/treaties/index.html>

Legislation in force

The texts are arranged under twenty main chapter headings. Legislation relating to agriculture, biotechnology, organic farming, foodstuffs, etc. can be found under heading 03 "Agriculture" and heading 15 "Environment, Consumers and Health Protection". On this site you can find the initial legislation and all the amendments as published in the Official Journal.

A few tips to perform a search:

- click on the category and select one of the subcategories or click on the alphabetical index
- use the search engine: type in the document's 8-digit identification number which starts with a "3" followed by the year followed by a letter code identifying the type of document (D=Decision, R=Regulation, L=Directive) and then the number of the document.
Examples: Decision 68/183/EEC=368D0183, Regulation 1139/98=398R1139, Directive 96/8/EC=396L0008

- include the 8-digit reference number and year in the following URL:

http://europa.eu.int/eur-lex/en/lif/dat/year/en_refnumber.html

Examples: to retrieve Decision 68/183/EEC, Regulation 1139/98 or Directive 96/8/EC the address would be:

http://europa.eu.int/eur-lex/en/lif/dat/1968/en_368D0183.html

http://europa.eu.int/eur-lex/en/lif/dat/1998/en_398R1139.html

http://europa.eu.int/eur-lex/en/lif/dat/1996/en_396L0008.html

<http://europa.eu.int/eur-lex/en/lif/index.html>

Consolidated texts

"Consolidated" means that the texts of all the amendments have been incorporated into the text of the basic act. The consolidated texts are for information purposes only and therefore not legally binding. The texts are available on two sites on the European Server: the "Eur-lex" and the "Consleg" website. Please note that not all EU legislation is available through this service.

A few tips to perform a search on the "Eur-lex" website:

- click on the heading number and select one of the subcategories
- click on the chronological index which will allow you to search by year of adoption
- use the search engine: type in keywords, reference number and date of document

<http://europa.eu.int/comm/sg/consolid/en/accueil.htm>

On the "Consleg" website, the chronological index lists a first series of consolidated community legislation on the Common Agricultural Policy. Consolidation of agricultural legislation is expected to be completed by 2001.

If you click on "Consolidated texts" you will find the same 20 thematic chapters as on the Eur-lex website. Consolidated versions of specific pieces of legislation can be accessed directly by including the document's reference number in the following URL:

<http://europa.eu.int/celex/consleg/yyTnnnn/en/cov.htm> (yy=year, T=type of document, nnnn=reference number).

Examples: to retrieve the consolidated version of Decision 68/183/EEC, Regulation 1139/98 or Directive 96/8/EC the address would be:

<http://europa.eu.int/celex/consleg/68D0183/en/cov.htm>

<http://europa.eu.int/celex/consleg/98R1139/en/cov.htm>

<http://europa.eu.int/celex/consleg/96L0008/en/cov.htm>

http://europa.eu.int/celex/consleg/home_en.htm

Preparatory Acts

List of Commission proposals that have not yet been adopted.

<http://europa.eu.int/eur-lex/en/com/index.html>

Case Law

Recent case-law of the European Court of Justice and the Court of First Instance is available.

<http://europa.eu.int/jurisp/cgi-bin/form.pl?lang=en>

AGAINST PAYMENT

Celex database

Celex is a multilingual database covering a wide range of EU legal acts. Coverage includes most acts published in the Official Journal, international agreements, merger decisions, etc. Database searches are easy and can be based on several criteria: keywords, type of document, reference number and date of adoption/publication. Documents can be viewed and downloaded.

- The Celex database is available as a web service. Costs for consulting the database involve a fixed fee for

each search plus an additional fee to view documents. Details are available at <http://europa.eu.int/celex>

- The Celex database is also available on CD-Roms published under license of the EC's Publication Office. More information is available at <http://eur-op.eu.int/en/general/b4.htm#lic>

Document delivery service

- The EUDOR on-line delivery service provides easy access to EU legislation via an image archive, implying that you do not have wordprocessing abilities such as word searches, or cut and paste. EUDOR allows customers to see the title and basic information of the document they are looking for. Customers can then order the whole document to be delivered by post, fax or electronic file transfer.

<http://www.eudor.com/>

- Electronic versions of single pieces of EU legislation in Formex, Winword 6.0 or WordPerfect 5.1. can also be ordered from:

Office of Publications of the European Communities
UNIT 4 - SALES AND COPYRIGHT MANAGEMENT
DOCUMENT DELIVERY
Tel: (32-2) 295 60 61
Fax: (32-2) 299 09 55

Sales Offices

Subscriptions and paper editions of the Official Journal can also be obtained from one of the sales offices. Sales offices in the U.S.:

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Fax (800) 865 3450
E-mail: query@bernan.com

European Document Research
1100 Seventeenth Street, N.W. Suite 301
Washington, D.C. 20036
Tel. (202) 785 8594
Fax (202) 785 8589
E-mail: edrwash@erols.com

URL: <http://www.bernan.com>

URL: <http://www.eudoc.com/>

Advanced Information Databases, Inc. PSI-USA

23205 Gratiot Avenue

Eastpointe, MI 48021

Tel. (800) 890 1692

Fax (519) 539 3176

E-mail: adinfo@adinfo.com

URL: <http://www.adinfo.com>

1249 Wyoming Street, P.O. box 1526

Golden, CO 80403

Tel. (303) 277 1137

Fax (303) 277 9419

E-mail: connelly@psi-usa.com

URL: <http://www.psi.usa.com>

Note: this is not an endorsement of any of the services offered by these companies. The U.S. Government is not responsible for performance, or lack thereof, of these companies.

APPENDIX III. LIST OF GENERALLY PERMITTED FOOD ADDITIVES AT “*QUANTUM SATIS*”

* no maximum level is specified

Colors

E101	(i)	Riboflavin
	(ii)	Riboflavin-5'-phosphate
E140		Chlorophylls and chlorophyllins
E141		Copper complexes of chlorophylls and chlorophyllins
E150a		Plain caramel
E150b		Caustic sulphite caramel
E150c		Ammonia caramel
E150d		Sulphite ammonia caramel
E153		Vegetable carbon
E160a		Carotenes
E160c		Paprika extract, capsanthin, capsorubin
E162		Beetroot Red, betanin
E163		Anthocyanins
E170		Calcium carbonate
E171		Titanium dioxide
E172		Iron oxides and hydroxides

Miscellaneous Additives

E 170	Calcium carbonates (i) Calcium carbonate (ii) Calcium hydrogen carbonate
E260	Acetic acid
E261	Potassium acetate
E262	Sodium acetates (i) Sodium acetate (ii) Sodium hydrogen acetate (sodium diacetate)
E263	Calcium acetate
E270	Lactic acid
E290	Carbon dioxide*
E296	Malic acid
E300	Ascorbic acid
E301	Sodium ascorbate
E302	Calcium ascorbate
E304	Fatty acid esters of ascorbic acid (i) Ascorbyl palmitate (ii) Ascorbyl stearate
E306	Tocopherol-rich extract
E307	Alph-tocopherol
E308	Gamma-tocopherol
E309	Delta-tocopherol

E322	Lecithins
E325	Sodium Lactate
E326	Potassium lactate
E327	Calcium lactate
E330	Citric acid
E331	Sodium citrate
	(i) Monosodium citrate
	(i) Disodium citrate
	(iii) Trisodium citrate
E332	Potassium citrates
	(i) Monopotassium citrate
	(ii) Tripotassium citrate
E333	Calcium citrates
	(i) Monocalcium citrate
	(ii) Dicalcium citrate
	(iii) Tricalcium citrate
E334	Tartaric acid (L(+)-)
E335	Sodium tartrates
	(i) Monosodium tartrate
	(ii) Dipotassium tartrate
E336	Potassium tartrate
	(i) Monopotassium tartrate
	(ii) Dipotassium tartrate
E337	Sodium potassium tartrate
E350	Sodium malates
	(i) Sodium malate
	(ii) Sodium hydrogen malate

E351	Potassium malate
E352	Calcium malates
	(i) Calcium malate
	(ii) Calcium hydrogen malate
E354	Calcium tartrate
E380	Triammonium citrate
E400	Alginic acid
E401	Sodium alginate
E402	Potassium alginate
E403	Ammonium alginate
E404	Calcium alginate
E406	Agar
E407	Carrageenan
E407a	Processed eucheama seaweed
E410	Locust bean gum#
E412	Guar gum#
E413	Tragacanth
E414	Acacia gum (gum arabic)
E415	Xanthan gum#
E417	Tara gum#
E418	Gellan gum

E422	Glycerol
E440	Pectins
	(i) pectin
	(ii) amidated pectin
E460	Cellulose
	(i) Microcrystalline cellulose
	(ii) Powdered cellulose
E461	Methyl cellulose
E463	Hydroxypropyl cellulose
E464	Hydroxypropyl methyl cellulose
E465	Ethyl methyl cellulose
E466	Carboxy methyl cellulose
	Sodium carboxy methyl cellulose
E469	Enzymatically hydrolysed carboxy methyl cellulose
E470a	Sodium, potassium and calcium salts of fatty acids
E470b	Magnesium salts of fatty acids
E471	Mono- and diglycerides of fatty acids
E472a	Acetic acid esters of mono- and diglycerides of fatty acids
E472b	Lactic acid esters of mono- and diglycerides of fatty acids
E472c	Citric acid esters of mono- and diglycerides of fatty acids
E472d	Tartaric acid esters of mono- and diglycerides of fatty acids
E472e	Mono- and diacetyl tartaric acid esters of mono- and diglycerides of fatty acids

E472f	Mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acids
E500	Sodium carbonates <ul style="list-style-type: none">(i) Sodium carbonate(ii) Sodium hydrogen carbonate(iii) Sodium sesquicarbonate
E501	Potassium carbonates <ul style="list-style-type: none">(i) Potassium carbonate(ii) Potassium hydrogen carbonate
E503	Ammonium carbonates <ul style="list-style-type: none">(i) Ammonium carbonate(ii) Ammonium hydrogen carbonate
E504	Magnesium carbonates <ul style="list-style-type: none">(i) Magnesium carbonate(ii) Magnesium hydroxide carbonate (syn: Magnesium hydrogen carbonate)
E507	Hydrochloric acid
E508	Potassium chloride
E509	Calcium chloride
E511	Magnesium chloride
E513	Sulphuric acid
E514	Sodium sulphates <ul style="list-style-type: none">(i) Sodium sulphate(ii) Sodium hydrogen sulphate
E515	Potassium sulphates <ul style="list-style-type: none">(i) Potassium sulphate(ii) Potassium hydrogen sulphate
E516	Calcium sulphate

E524	Sodium hydroxide
E525	Potassium hydroxide
E526	Calcium hydroxide
E527	Ammonium hydroxide
E528	Magnesium hydroxide
E529	Calcium oxide
E530	Magnesium oxide
E570	Fatty acids
E574	Gluconic acid
E575	Glucono-delta-lactone
E576	Sodium gluconate
E577	Potassium gluconate
E578	Calcium gluconate
E640	Glycine and its sodium salt
E920	L-Cysteine (1)
E938	Argon*
E939	Helium*
E941	Nitrogen*
E942	Nitrous oxide*
E948	Oxygen*

E1103	Invertase
E1200	Polydextroxe
E1404	Oxidized starch
E1410	Monostarch phosphate
E1412	Distarch phosphate
E1413	Phosphated distarch phosphate
E1414	Acetylated distarch phosphate
E1420	Acetylated starch
E1422	Acetylated distarch adipate
E1440	Hydroxy propyl starch
E1442	Hydroxy propyl distarch phosphate
E1450	Starch sodium octenyl succinate
E1451	Acetylated oxidised starch

(1) may be used only as a flour treatment agent

* these substances may also be used in the foodstuffs referred to in art. 2(3) of directive 95/2/EC

these substances may not be used to produce dehydrated foodstuffs intended to rehydrate on ingestion